

Food and Drug Administration, HHS

§ 203.30

or trade, or offer to sell, purchase, or trade any prescription drug that was:

- (a) Purchased by a public or private hospital or other health care entity; or
- (b) Donated or supplied at a reduced price to a charitable organization.

§ 203.22 Exclusions.

Section 203.20 does not apply to:

(a) The purchase or other acquisition of a drug for its own use by a hospital or other health care entity that is a member of a group purchasing organization from the group purchasing organization or from other hospitals or health care entities that are members of the organization.

(b) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization to a nonprofit affiliate of the organization to the extent otherwise permitted by law.

(c) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other health care entities that are under common control.

(d) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons.

(e) The sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug under a valid prescription.

(f) The sale, purchase, or trade of a drug or the offer to sell, purchase, or trade a drug by hospitals or health care entities owned or operated by Federal, State, or local governmental units to other hospitals or health care entities owned or operated by Federal, State, or local governmental units.

(g) The sale, purchase, or trade of, or the offer to sell, purchase, or trade blood or blood components intended for transfusion.

§ 203.23 Returns.

The return of a prescription drug purchased by a hospital or health care entity or acquired at a reduced price by or donated to a charitable institution is exempt from the prohibitions in § 203.20, provided that:

- (a) The hospital, health care entity, or charitable institution documents

the return by filling out a credit memo specifying:

(1) The name and address of the hospital, health care entity, or charitable institution;

(2) The name and address of the manufacturer or wholesale distributor from which it was acquired;

(3) The product name and lot or control number;

(4) The quantity returned; and

(5) The date of the return.

(b) The hospital, health care entity, or charitable institution forwards a copy of each credit memo to the manufacturer and retains a copy of each credit memo for its records;

(c) Any drugs returned to a manufacturer or wholesale distributor are kept under proper conditions for storage, handling, and shipping, and written documentation showing that proper conditions were maintained is provided to the manufacturer or wholesale distributor to which the drugs are returned.

Subpart D—Samples

§ 203.30 Sample distribution by mail or common carrier.

(a) *Requirements for drug sample distribution by mail or common carrier.* A manufacturer or authorized distributor of record may distribute a drug sample to a practitioner licensed to prescribe the drug that is to be sampled or, at the written request of a licensed practitioner, to the pharmacy of a hospital or other health care entity, by mail or common carrier, provided that:

(1) The licensed practitioner executes and submits a written request to the manufacturer or authorized distributor of record, as set forth in paragraph (b) of this section, before the delivery of the drug sample;

(2) The manufacturer or authorized distributor of record verifies with the appropriate State authority that the practitioner requesting the drug sample is licensed or authorized under State law to prescribe the drug product;

(3) The recipient executes a written receipt, as set forth in paragraph (c) of this section, when the drug sample is delivered; and